



Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

VIA FEDERAL EXPRESS

Ref: Customs Entry No: G73-2004779-6
Products: Mucuous Specimen Trap
Nasogastric Tube
Latex Catheter and Irrigation Sets

WARNING LETTER

FLA-00-34

February 25, 2000

North American Purchase & Trade
104 Crandon Boulevard
Suite 317
Key Biscayne, Florida 33149-1542

Dear Madam/Sir:

The Food and Drug Administration (FDA) attempted to examine a shipment of various devices described above and offered for entry into the United States by your firm on December 28, 1999, under the above referenced entry number, and found that the entire shipment was not available for FDA examination. Title 21, Code of Federal Regulations (21CFR), Section 1.90 requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. Since the devices were not held intact, we have requested the U. S. Customs Service (Customs) to order redelivery of the devices which have been distributed without a release from FDA (copy enclosed).

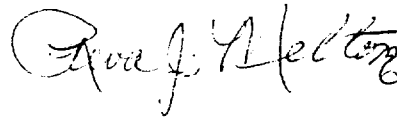
Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of further shipments. It is your responsibility, as the importer, to ensure that imported products meet all the requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

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We request a response in writing within fifteen (15) working days of receipt of this letter outlining the specific steps you have taken to correct the violation. Your response should include an explanation of each step being taken to prevent the recurrence of the violation. In the event that the product is still available for examination, you should inform Customs and FDA if and when redelivery is accomplished.

Your written reply should be addressed to the Food and Drug Administration, Attention: Paul R. Bagdikian, Compliance Officer, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,



Reva J. Melton
Acting Director
Florida District

cc: Port Director
U. S. Customs Service
P. O. Box 02-580
Miami, Florida 33102-5280

Import Commodity Group International
9270 N.W. 100th Street
Miami, Florida 33178